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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,438	09/05/2003	Edward J. Seppi	VM7010742001	8465
23639	7590	10/27/2005	EXAMINER	
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO CENTER 18 FLOOR SAN FRANCISCO, CA 94111-4067			SUCHECKI, KRISTYNA	
			ART UNIT	PAPER NUMBER
			2882	

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

H.A

Office Action Summary

Application No.

10/656,438

Applicant(s)

SEPPI ET AL.

Examiner

Krystyna Suchecki

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39, 42-49 and 54-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39, 42-49, 54-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 31-39, 42- 49 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey (US 2003/0048868).
3. Regarding Claims 1 and 3, Bailey teaches a radiation process wherein a first beam and a second beam can have low intensities (Paragraphs 4 and 37) and further teaches a radiation method, comprising: illuminating an object with a first beam (22A) at a first energy level (Paragraph 39); determining a first image of the object formed by the first beam (Paragraphs 45 and 50); determining configuration data using the first image (Paragraph 49); illuminating the object with a second beam (22B) at a second energy level (Paragraph 44); determining a second image of the object formed by the second beam (Paragraphs 45 and 50); determining radiation absorption data using the second image (Paragraphs 43-51); and determining a radiation treatment plan using the configuration data and the radiation absorption data (Paragraphs 33, 43-51).
4. Regarding Claim 45, Figures 1-3 of Bailey teach an apparatus for irradiating an object, comprising: a platform (60) for supporting an object; a first beam source (22A)

configured to generate a first radiation beam (30A) at a first intensity level and a second radiation beam at a second intensity level toward the platform (Paragraphs 43-44); a beam adjuster in front of the first beam source for adjusting a radiation beam directed from the first beam source (Paragraph 45); a projection detector (24A) configured to generate a first image of the object illuminated by the first radiation beam at the first intensity level; and a control module (82 and Paragraph 53) coupled to the projection detector and to the beam adjuster. Bailey teaches a beam adjuster since a fan beam is formed by adjusting the spread of an X-ray beam to conform to a fan shape.

5. Regarding Claim 46, Bailey teaches the apparatus of claim 45, further comprising a second beam source (22B) configured to generate an image beam toward the platform, wherein the projection detector is further configured to generate a second image of the object illuminated by the image beam (Paragraphs 43-44 and 50).

6. Regarding Claims 47, 48 and 54, Bailey teaches the apparatus of claim 45, wherein the control module is configured to develop a radiation treatment plan based on the first image or based on one or both of the first image and the second image (Paragraphs 48-54).

7. Regarding Claim 49, Bailey teaches the apparatus of claim 45, wherein the control module is configured to adjust one or a combination of a shape, an intensity, and a direction of the second radiation beam (Paragraphs 43-47, 50 and 53-54).

8. Regarding Claims 31 and 42, Bailey teaches a radiation process and system, comprising: illuminating an object with a treatment beam in accordance with a treatment plan (Paragraphs 48-51); determining an image of the object formed by the treatment

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beam (Paragraphs 33, 48 and 53-54); determining radiation absorption data using the image (Paragraph 54, since the dose administered is monitored to determine properness of the exposure, the detector is monitoring absorption data); evaluating an execution of the treatment plan based on the radiation absorption data (Paragraphs 48 and 53-54); and determining the treatment plan (Paragraph 28); wherein at least a portion of the determining the treatment plan and at least a portion of the illuminating the object with the treatment beam are performed during a same patient session (Paragraphs 26-32). Bailey teaches the imaging and treatment "during a same patient session" since emphasis is placed upon not allowing the patient to leave the imaging table between images. The "Background of the Invention" emphasizes a need in the art to complete both pre-treatment imaging and treatment without a need for marking or releasing a patient between exposures. In other words, Bailey's goal is to image, plan a treatment dose, and image a treatment beam in a same patient session.

9. Regarding Claims 32-34 and 43, Bailey teaches a process and system of adjusting the treatment beam, wherein the adjusting comprises one or a combination of changing a direction, a shape, and an intensity of the treatment beam based upon determined configuration data of the object (Paragraphs 49, 51-54).

10. Regarding Claim 35, Bailey teaches the process of claim 34, wherein the determining the configuration data comprises illuminating the object with an image beam; determining an image formed by the image beam; and determining the configuration data using the image formed by the image beam (Paragraphs 47-50).

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11. Regarding Claim 36, Bailey teaches evaluating performed based on the configuration data (Paragraphs 47-50 and 53-54).
12. Regarding Claim 37, Bailey teaches a method and system for adjusting the treatment beam based on the configuration data (Paragraph 49).
13. Regarding Claims 38 and 44, Bailey teaches a method and system comprising gating an operation of the treatment beam based on the configuration data (Paragraphs 49 and 54, since Bailey evaluates and treats at a certain angle, then adjusts the device to evaluate and treat at a second angle, the method and system are gated based upon the configuration data).
14. Regarding Claims 39, Bailey teaches the process of claim 31, further comprising verifying the treatment plan before illuminating the object with the treatment beam (Paragraphs 21, 23, 33 and 53-54).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1, 4, 6-12, 14-17 and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey in view of Swerdloff (US 5,661,773).
17. Regarding Claims 1, 14 and 55-58, Bailey teaches a radiation method and system, comprising: illuminating an object with a first beam at a first energy level (Paragraph 39); determining a first image of the object formed by the first beam

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(Paragraphs 45); determining configuration data using the first image (Paragraph 49); illuminating the object with a second beam at a second energy level (Paragraphs 49-54); determining a second image of the object formed by the second beam (Paragraphs 48-51); and determining radiation absorption data using the second image (Paragraphs 49-51).

18. Bailey does not explicitly teach determining a radiation treatment plan using the configuration data and the radiation absorption data and instead teaches treatment monitoring.

19. However, Swerdloff teaches a system and method for monitoring a detector for a pre-treatment image, and during a treatment dose, in order to monitor the dose administered and also to update a treatment plan in accordance with images created by the detector in response to the dose (Column 17, line 30- Column 18, line 43). A treatment plan is created by way of acquiring a new dose for a patient's next treatment, by modifying an error dose as generated in response to a comparison of the detected dose and a desired dose for the benefit of correcting for dose errors (Id.).

20. Therefor, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the treatment plan comparison, creation and modification system and method of Swerdloff in the method and system of Bailey for the benefit of correcting for dose errors (Column 17, line 30- Column 18, line 43).

21. Regarding Claim 4, Bailey teaches a radiation process having a first energy level beam for imaging and a second energy level imaging beam as above for claim 1.

22. Bailey fails to teach intensities wherein the first beam has an intensity between approximately 1 Rad and 20 Rad, and the second beam has an intensity between approximately 250 Rad and 1000 Rad.

23. Swerdloff teaches that a preliminary image of an object for treatment should be made with a beam of a first energy level wherein the beam has an intensity between approximately 1 and 20 Rad (Figures 19-21). A first image is made, and the a second energy level beam is used to treat an area of an object with a second energy level between 250 and 1000 Rad (Column 14, lines 1-7). The treatment is tracked as an imaged dose map (item 90). The second image is used to track whether the dose was administered accurately (Abstract).

24. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Rad values of Swerdloff in the process of Bailey since conventional image and treatment intensities are used to treat an object and create first and second images of an object. By tracking the Rad values administered, Bailey can better track the dose administered for accuracy (Swerdloff, Abstract).

25. Regarding Claim 6, Bailey teaches the method of claim 1, further comprising adjusting an intensity of the second beam during a session (Paragraph 53, since a power supply is varied).

26. Regarding Claims 7 and 8, Bailey teaches the method of claim 1, wherein the illuminating the object with the first beam and the illuminating the object with the second beam are performed in alternating pulses and wherein the illuminating the object with

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the first beam and the illuminating the object with the second beam are performed sequentially (Paragraphs 43-46 and 50).

27. Regarding Claims 9 and 15, Bailey in view of Swerdloff teaches a method and system, wherein the determining configuration data comprises comparing data associated with the first image with data regarding configuration of the object specified in a treatment prescription (Paragraphs 53-54 as combined with Swerdloff Column 17, line 30- Column 18, line 43, above).

28. Regarding Claims 10 and 16, Bailey teaches a method and system, wherein the determining radiation absorption data comprises calculating a radiation absorption rate in the object. [Bailey teaches dose tracking (Paragraph 54), which is numerically linked to the absorption rate since the rate must be known in order to determine the dose.]

29. Regarding Claims 11 and 17, Bailey in view of Swerdloff teaches a method and system, further comprising storing the configuration data and the radiation absorption data in a computer readable medium (Bailey, Paragraphs 48 and 53-54 and Swerdloff, Column 18, lines 25-43).

30. Regarding Claim 12, Bailey teaches the method of claim 1, wherein the configuration data comprises one or a combination of location, size, and shape of the object (Paragraphs 49-52).

31. Claims 2, 18-24 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey in view of Swerdloff as applied to claims 1 and 14 above, and further in view of Ruchala (US 6,618,467).

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32. Regarding Claims 2, 18, and 26, Bailey in view of Swerdloff teaches a method and system for radiation imaging and therapy as above having first and second imaging beams.

33. Bailey in view of Swerdloff fails to teach voltages for the first and second imaging beams.

34. Ruchala teaches that conventional first imaging beams could be in the kilovoltage range, and second imaging beams can be on a megavoltage range (Column 1, lines 56-67). The difference in ranges allows for a low energy pre-scanning image to be made, and a second image to be made during high energy treatment. The first and second images are used in concert to create a treatment plan (Column 1, line 56-Column 2, line 14).

35. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the kilovoltage and megavoltage energy levels of Ruchala in the system of Bailey as modified by Swerdloff for the benefit of creating a pre-scanning image to be used with, and for the creation of, a treatment plan.

36. Regarding Claims 20 and 27, Bailey teaches a method and system further comprising adjusting an intensity of the second beam during a session (Paragraph 53, since a power supply is controlled, which allows varied intensities on the sources).

37. Regarding Claims 21 and 28, Bailey in view of Swerdloff teaches a method and system, wherein the determining configuration data comprises comparing data associated with the first image with data regarding configuration of the object specified

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in a treatment prescription (Paragraphs 49, 51, 53-54 as combined with Swerdloff Column 17, line 30- Column 18, line 43, above).

38. Regarding Claims 22 and 29, Bailey teaches a method and system, wherein the determining radiation absorption data comprises calculating a radiation absorption rate in the object. [Bailey teaches dose tracking (Paragraph 54), which is numerically linked to the absorption rate since the rate must be known in order to determine the dose.]

39. Regarding Claims 23 and 30, Bailey in view of Swerdloff teaches a method and system, further comprising storing the configuration data and the radiation absorption data in a computer readable medium (Bailey, Paragraphs 48 and 53-54 and Swerdloff, Column 18, lines 25-43).

40. Regarding Claim 24, Bailey teaches a method, wherein the configuration data comprises one or a combination of location, size, and shape of the object (Paragraphs 49-52).

41. Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey and Swerdloff as above for claim 1, and further in view of McNutt (US 6,735,277).

42. Regarding Claims 5 and 13, Bailey teaches a method wherein the radiation treatment plan is configured for use in a computed fan therapy where a slices are defined by a collimator (Paragraph 25) as a source rotates about a patient (Paragraphs 41-47) to create a computer generated two-dimensional dose of radiation (Paragraphs 48-50) for adaptive, single visit treatment (Paragraphs 33 and 53-54). A power supply controls a radiation source (Paragraph 53).

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43. Bailey fails to teach computed cone therapy or a second beam having a constant intensity during a session.

44. McNutt teaches an imaging and treatment method where fan therapy is an alternative of cone therapy (Column 4, line 2; Column 5, lines 45-65). There are tradeoffs between the two, one being that the cone therapy requires a more complicated collimator for constant intensity step-and-shoot applications, versus the need to spiral scan in a fan-beam system (Id.). The cone beam system would thereby afford more stability as the system could operate in a stationary mode with less vibration from moving parts, thereby making the application of dose radiation more accurate.

45. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the alternative constant intensity computed cone beam therapy of McNutt in the adaptive treatment system of Bailey since the step-and-shoot operation afforded by McNutt would allow less interfering vibration during treatment. The cone beam therapy would still further Bailey's goal of planning and treatment in a single visit, while not interfering with the adaptive treatment planning operations.

46. Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey, Swerdloff and Ruchala as above for claim 18, and further in view of McNutt (US 6,735,277).

47. Regarding Claims 19 and 25, Bailey teaches a method wherein the radiation treatment plan is configured for use in a computed fan therapy where a slices are

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defined by a collimator (Paragraph 25) as a source rotates about a patient (Paragraphs 41-47) to create a computer generated two-dimensional dose of radiation (Paragraphs 48-50) for adaptive, single visit treatment (Paragraphs 33 and 53-54). A power supply controls a radiation source (Paragraph 53).

48. Bailey fails to teach computed cone therapy or a second beam having a constant intensity during a session.

49. McNutt teaches an imaging and treatment method where fan therapy is an alternative of cone therapy (Column 4, line 2; Column 5, lines 45-65). There are tradeoffs between the two, one being that the cone therapy requires a more complicated collimator for constant intensity step-and-shoot applications, versus the need to spiral scan in a fan-beam system (Id.). The cone beam system would thereby afford more stability as the system could operate in a stationary mode with less vibration from moving parts, thereby making the application of dose radiation more accurate.

50. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the alternative constant intensity computed cone beam therapy of McNutt in the adaptive treatment system of Bailey since the step-and-shoot operation afforded by McNutt would allow less interfering vibration during treatment. The cone beam therapy would still further Bailey's goal of planning and treatment in a single visit, while not interfering with the adaptive treatment planning operations.

Response to Arguments

Applicant's arguments, see Response, filed 06/30/05, with respect to the rejection(s) of claim(s) 1-49 under Bailey have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bailey and other, as set forth above.

With respect to arguments that Bailey fails to teach treatment planning, Examiner has applied a more direct showing of treatment planning. Bailey implies a desire to plan subsequent treatment by comparing images (Paragraph 53). Treatment is "maximized" by comparison, which implies updating and modifying the course of treatment. However, this implication is not as explicit as the teachings of Swerdloff, and so a 103 rejection has been applied as set forth above to more fully illustrate treatment planning.

Applicant's arguments with respect to claims 31 and 42 are not persuasive. Applicant's attention is drawn to the language of the claim, which does not require the treatment plan to be determined at any specific point, such as after a treatment beam is administered. Since Bailey teaches a determination of a plan for treatment before therapy and after planning-imaging, a treatment plan is determined.

With respect to arguments involving "a same patient session", as set forth above, the goal of Bailey's invention is to avoid multiple patient sessions for treatment planning and therapy. Bailey aims at eliminating a session, and eliminating re-alignment means, by combining the planning and first treatment sessions wherein a patient does not leave the imaging table. Therefor, Applicant's arguments that treatment and planning are not done "in a same session" are not persuasive.

Applicant's arguments with respect to claim 45 are persuasive. However, a new rejection has been set forth above.

With respect to claims 18 and 26, Ruchala has been relied upon to show a treatment beam in the MeV level. Both Ruchala and Bailey teach imaging with this level of radiation. As set forth in paragraph 54 of Bailey, proper dose administration is ensured. This implies that the amount of radiation absorbed by the patient is considered in the detection and evaluation processes. With the addition of Swerdloff, who considers more explicitly the use of absorption data for determining treatment beam efficacy, Bailey's implications have been addressed by the combination rejection set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krystyna Suchecki whose telephone number is (571) 272-2495. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Craig E Church

Craig E. Church
Primary Examiner